

JUL 1 9 2011

# GE Healthcare 510(k) Premarket Notification Submission Optima XR120

### 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: May 6, 2011

Submitter: GE Healthcare, (GE Medical Systems, LLC)

3000 N. Grandview Blvd. Waukesha, WI 53188

Primary Contact Person: Nidhi Chaudhary

Regulatory Affairs Leader, X-Ray

GE Healthcare, (GE Medical Systems, LLC) Telephone: 414-721-2899; Fax: 414-918-8184

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Secondary Contact Person: David Blonski

Regulatory Affairs Director, X-Ray

GE Healthcare, (GE Medical Systems, LLC) Telephone: 262-513-4072; Fax: 262-364-2509

e-mail: David.Blonski@ge.com

Device: Trade Name: GE Healthcare Optima™ XR120

Common/Usual Name: Optima XR120

Classification Names: Optima XR120

Product Code: Class II, IZL, System, X-ray, Mobile, 21 CFR 892.1720

Predicate Device(s): GE Definium AMX700, Model AMX 700 K052897

Intended Use: The Optima XR120 is indicated for use in generating

radiographic images of human anatomy. It is intended for general-purpose diagnostic procedures. It is capable of generating images on film or digitally. This device is not

intended for mammographic applications.



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Technology:

The GE Healthcare Optima™ XR120 employs the same fundamental scientific technology as its predicate devices.

### <u>Determination of</u> Substantial Equivalence:

The Optima XR120 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

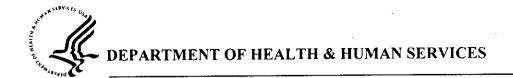
- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

### Summary of Clinical Tests:

The subject of this premarket submission, Optima XR120, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the GE Healthcare Optima<sup>TM</sup> XR120 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



Food and Drug Administration 10903 New Hampshire Avenue Document Control Room – WO66-G609 Silver Spring, MD 20993-0002

Ms. Nidhi Chaudhary Regulatory Affairs Leader, X-ray GE Medical Systems, LLC 3000 N. Grandview Blvd. WAUKESHA WI 53188

Re: K111304

Trade/Device Name: Optima XR120 Regulation Number: 21 CFR 892.1720 Regulation Name: Mobile x-ray system

Regulatory Class: II

Product Code: IXL and MQB

Dated: May 7, 2011 Received: May 9, 2011 JUL 1 9 2011

### Dear Ms. Chaudhary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.

Director

Division of Radiological Devices Office of In Vitro Diagnostic Device **Evaluation and Safety** 

Mary Startel

Center for Devices and Radiological Health

Enclosure ·



## GE Healthcare

510(k) Premarket Notification Submission Optima XR120

510(k) Number (if known): K 111304

Device Name:

Optima XR120

#### **Indications for Use:**

The Optima XR120 is indicated for use in generating radiographic images of human anatomy. It is intended for general-purpose diagnostic procedures. It is capable of generating images on film or digitally. This device is not intended for mammographic applications.

Prescription Use\_x\_ (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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